Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13380

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Form Approved: OMB No. 0910-0291 Expires: 1/31/9
See OMB statement on reverse

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN

Page 1 of 2

CFSAN

FDA Use Only
Triage unit sequence # 98358
13380

A. Patient information

1. Patient Identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
In confidence	18	☐ female ☒ male	___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☒ death ___ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): 2/26/99

4. Date of this report (mo/day/yr): 2/27/99

5. Describe event or problem

Body builder ingested an unknown amount of a nutritional supplement called ULTIMATE ORANGE, (see attached website ad) prior to going to the gym. At the gym, pt had a seizure. CT scan ⇒ massive subarachnoid hemorrhage. Declared brain dead.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 ULTIMATE ORANGE
#2

2. Dose, frequency & route used
#1 PO
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 2/26/99
#2

4. Diagnosis for use (indication)
#1 [redacted] BODY BUILDING
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
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10. Concomitant medical products and therapy dates (exclude treatment of event)

MAR 1999 RECEIVED DOMESTIC PROGRAMS BRANCH

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

5. Expiration date (mo/day/yr)

6
model # ___
catalog # MAR 1999
serial # ___
lot # MEDWATCH CTU
other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1. Name & address	phone #
[redacted]	

2. Health professional?	3. Occupation	4. Also reported to
☒ yes ☐ no	PHARMACIST	☐ manufacturer ☐ user facility ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 MEDWATCH MEDICAL PRODUCTS REPORTING PROGRAM

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTC 98358

Center for Food Safety and Applied Nutrition
Food and Drug Administration

Memo

To: File (ARMS# 13380)

From: Lori A. Love, M.D., Ph.D
Director, Clinical Research and Review Staff
Office of Special Nutritionals

Date: August 2, 1999

Re: Adverse event with an ephedrine alkaloid-containing product

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I had originally obtained (on 03/04/99) the telephone number of the funeral home where the services for [redacted] were being held. On explaining why I was calling the funeral home personnel gave me the telephone numbers of Mr[redacted] parents [redacted] and [redacted] or [redacted]' work) and stated also that they would tell the parents that I called.

I called the parents [redacted] the mother and [redacted] the stepfather) of [redacted] on or about March 10, 1999, in an attempt to get further information about the death of their son. Because the mother did not understand English well, I mainly discussed this case with Mr. [redacted] who acted as the interpreter. The family had no information concerning the use of the product, Ultimate Orange. They did state, however, that [redacted] had been previously healthy. Ms [redacted] was going to the [redacted] area in the next week to collect her sons remaining possessions from college. She agreed that during this trip to talk to her son's roommates and friends about his use of any products and further to discuss her findings with me.

I spoke to the mother again (though her husband) about one week later after the initial call. Although she was able to talk to several of her son's roommates, she was not able to get any additional information on how her son might have used the product "Ultimate Orange." Further, the family indicated that they accepted the medical examiner's opinion that their son died of "natural causes." My impression from this discussion was the family did not want the further intrusion that would result if FDA were to press the investigation of this case. I, therefore, elected to end the call, after thanking them for their time and efforts and again offering my condolences

[redacted]

==========[redacted] Poison Control System==========

Date of Call: 02/26/99 --> Friday at 21:30 Case Number: [redacted]
Report Date: 03/03/99 Initial SPI: [redacted]

----------Patient Information----------

Patient: [redacted] Patient Phone: [redacted]
Age: 18 YR Sex->Male

----------Caller Information----------

Hospital Name [redacted]
ER Phone: [redacted]
Caller: [redacted] Relationship: [redacted]
City: [redacted] Zip: [redacted]
Caller Phone: [redacted]

----------Substance(s) Involved----------

Substance 1:ULTIMATE ORANGE
Contains:EPHEDRA
Generic 1:MISCELLANEOUS UNKNOWN DRUGS

Initial History / Case Detail----------

Time Since Exposure: 5 UNKNWN
WEIGHTLIFTER TOOK THEN NOTED H/A THEN HAD SEIZURE - HAS CLONUS, DECEREBRATE POSTURING, UNRESPONSIVE SUSPECTS INTRACRANIAL BLEED HR PUPILS PINPOINT LIKE PONTINE HEMORRAGE P WAS 110 NOW 70

Case Detail:
had used product prior to going to gym - started seizing at gym - asking if we know what's in product suspects sympathomimetic - friends say they use it to get energy prior to going to gym
a/p unknown product - not in poisindex - ephedrine type product likely - will try to have friends get product from home - getting supportive measures
(Edited:02/26/99-21:42:35 by [redacted]

11:37 Saturday 02/27/99. Patient was admitted to [redacted] last night, then transferred to [redacted] ICU this morning. Spoke with patient's nurse [redacted] CT done at [redacted] showed massive subarachnoid hemorrhage. Patient is now comatose and brain dead. Pupils are "blown", dilated and fixed. Found list of product (Ultimate Orange) ingredients on the Internet. Suspicion of Ephedra was correct, product also contains Guarana, green tea and ginseng. Also contains carbohydrates, milk derivatives, vitamins and minerals. FYI website seems useful, many supplements described, address is www.netrition.com. [redacted]
(Edited:02/27/99-11:53:56 by [redacted]/ROTATION STUDENT)

10:20 Monday 03/01/99 [redacted] to
S/O: Received a call earlier this morning from Connie Hardy at the FDA (202) 205-5124. She requests information on the case as a follow up to [redacted] MedWatch report. Obtained the patient's home phone number from [redacted] medical records department. Received a call from [redacted] patient relations, concerned about the fact that the patient's body was already released to the mortuary after weekend clearance from the [redacted]. Also received a call from [redacted] at the Medical
Examiner's office. The body was released to a mortuary, has already been enbalmed and is en route to [redacted] for burial or cremation. Phone numbers have been provided for all parties so that the Medical Examiner and the FDA can communicate. Will forward to [redacted].
(Edited:03/01/99-10:32:35 by [redacted]

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Coding Detail:
Human, Exposure, Acute, Single Exp, Male, Age 18YR, Reason General, ES-Own Residence, CS-HCF *Code, Caller Site Code [redacted] Ingestion, Flow-In or Enroute to [redacted] Flow-Admit/Critical Care, Initial Manage Site Code [redacted]
Observation ONLY, No Decontaminiation Coded, ~~Unable to follow-Pot. Toxic,~~ ? DEATH

Outcome Duration N/A, Tachycardia Coma-U, Sz (Mult./discrete)-U, Fever/Hyperthemia-U,

Hosp. close to [redacted] @ [redacted]

(-) in serum.

Trace Ephedrine in urine

[redacted]

Head CT - ? Berry aneurysm.